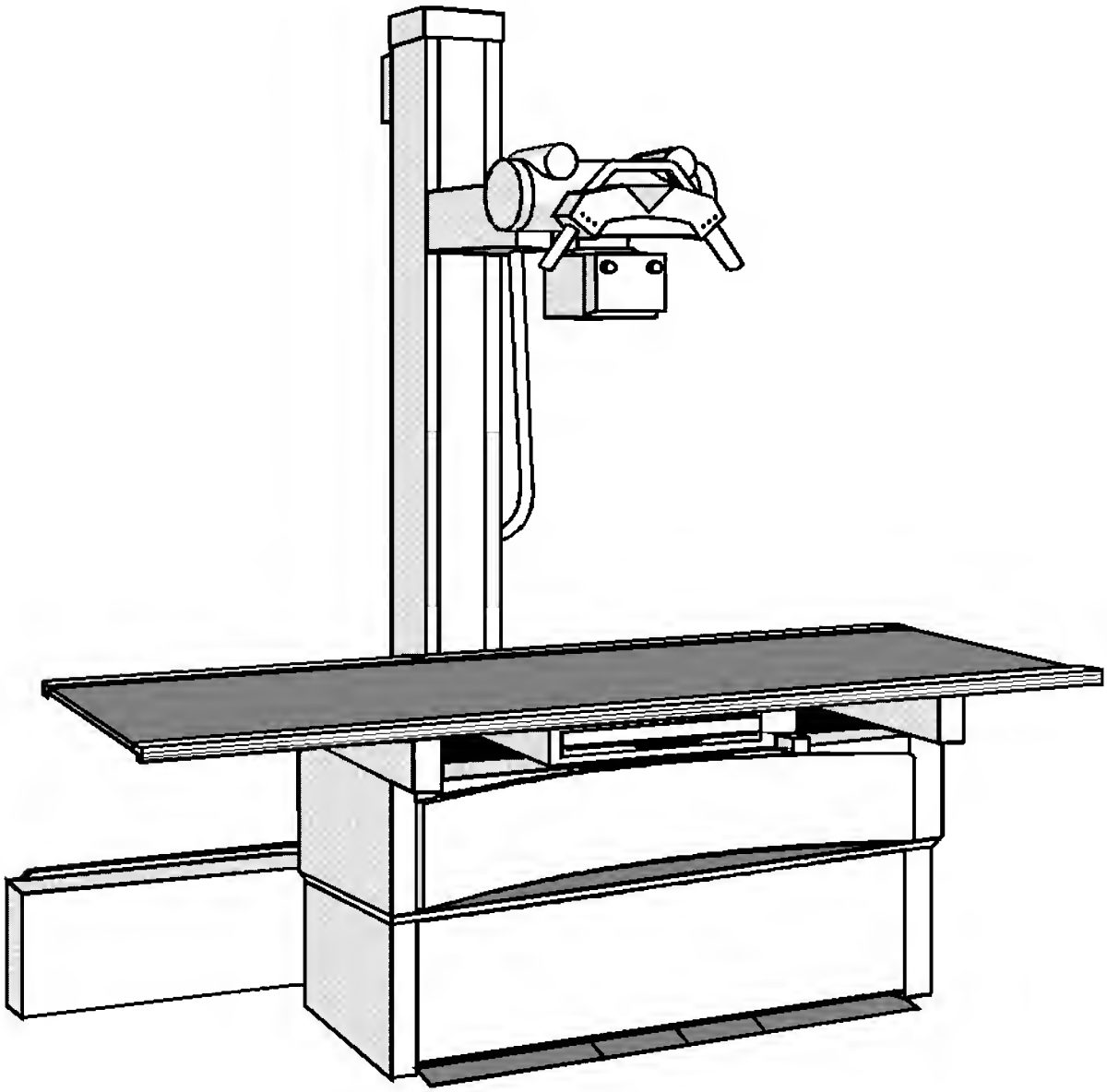
OPERATING INSTRUCTIONS COMBI ELEVATOR 2



CE 0125

English Edition

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Important Note:

To ensure proper operation of this product it is essential that the service personnel is familiar with the **"Operating Instructions"** which should be studied carefully before use.

Special attention is to be given to the chapter "Safety Notes"

The equipment must be used in accordance with the safety procedures described below, and must not be used for purposes other than those for which it was designed. The equipment may only be used by persons having recognized qualification, including adequate training in radiation protection, authorizing them to perform the examination or treatment carried out.

It is the responsibility of the user to ensure that the government regulations are observed in the installation and operation of the equipment.

Technical safety note:

Regulations

If legal regulations govern the operation of the above equipment, it is the responsibility of the operator to observe them.

For the safety of patients, operators and others, as well the efficient functioning of the equipment it is necessary to have periodic service inspections at 12-month intervals according to the maintenance schedule. Please apply to your service organisation for inspection and maintenance.

Inspections intervals must by all means meet the requirements of the respective legislation or government regulations.

Changes and additions to the product must comply with the relevant legislation as well as with the accepted standards of good manufacturing practice.

As manufacturer of electromedical systems, we assume responsibility for the safety of the equipment only if maintenance, repairs and changes are carried out exclusively by us or third parties expressly authorised by us to do so, and if defective parts relating to the safety of the equipment are replaced by genuine spare parts.

We recommend that the service personnel is being asked to issue a certificate specifying the kind and extend of things or work ranges. Also the certificate should show the date of repair, the name of the service company and the signature of the technician.

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Before operating the equipment, the operator must check all devices concerning the safe and efficient functioning.

If the user of this equipment likes to combine the unit with other units, components or assemblies and this can not be made clear from the technical data, he must question us as manufacturer or another expert to make sure that the safety of the patients and operator is given by the planned combination.

Product Safety

Electrical safety

Only trained service personnel are permitted to remove covers and panels from the x-ray equipment .

In the Federal Republic of Germany, the electrical installation of rooms used for medical purposes must conform to the provisions of the VDE Standard 0107. In all other countries, the provisions of the applicable local laws and regulations have priority.
The unit is only prepared for solid installation with an all poled separation from the power (ICE 601, Kap. 57.1).

Mechanical safety

It is the responsibility of the operator to ensure safety of patient while the unit is in operation by visual check, proper patient positioning, and use of devices that are provided.

Danger of injury

The solid black arrows and dotted lines in the illustration show areas which present potential Danger of Injury to operating personnal and patient from the equipment motion.

See next page.

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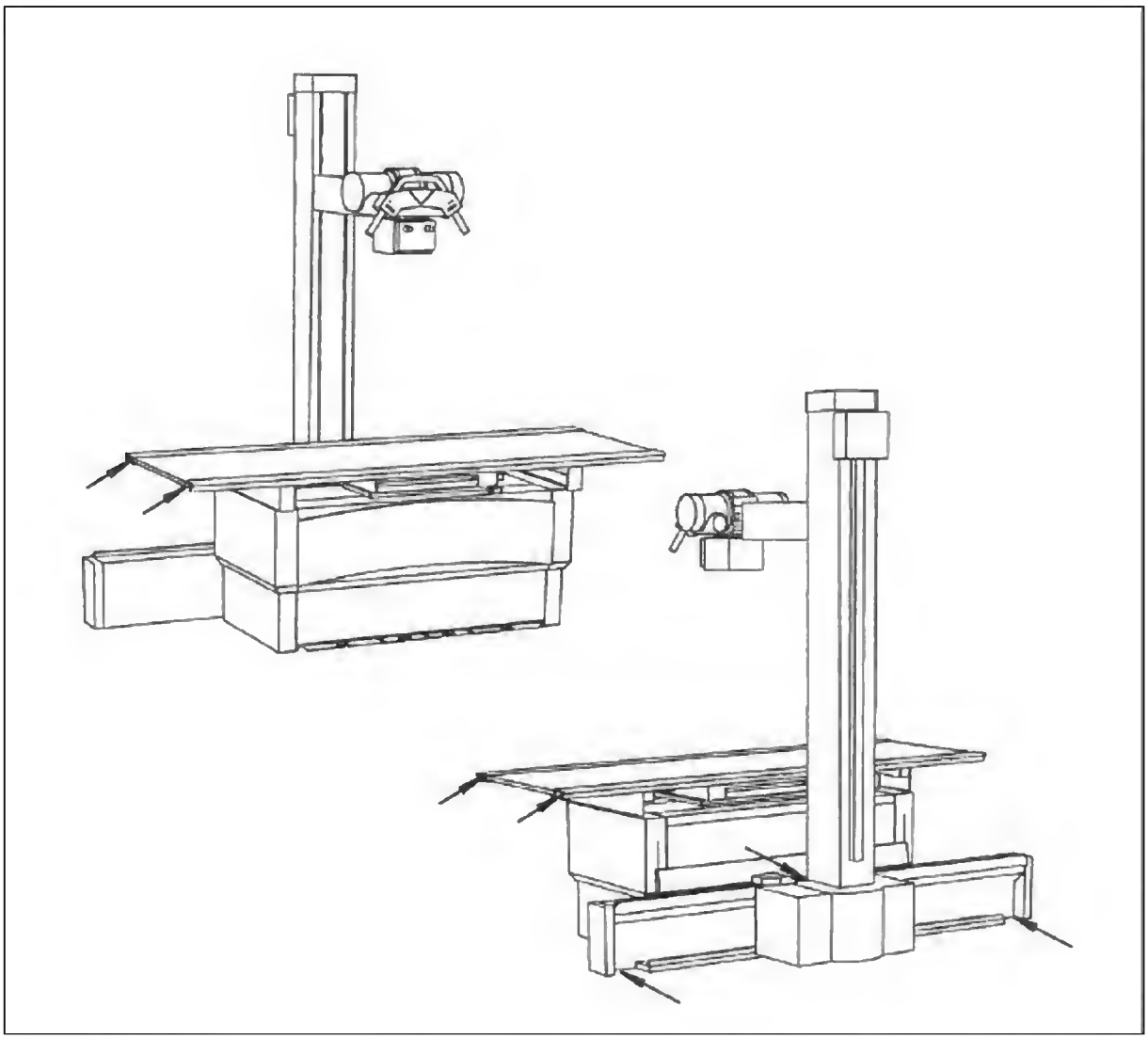

X-Ray Protection.

The unit has no controls with which radiation could be triggerd.
Exposure is triggerd only from the radiation-protected location of the generator.
The general radiation-protection measures must be observed.

In addition, we recommend the following:

1 Set the tube current as low as possible .
2 Limit the radiation field to the maximum possible extent.
3 Keep as fare away as possible.
4 Provide radiation protection for the patient.

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Explosion Protection

This equipment is not designed for use in areas where explosion hazard can take place.
Only skin cleansing agents may be used which form non-explosive mixtures with air.

Interference Suppression

The equipment complies with the EMC-requirements of the guideline 89/336 EWG. of
* Special board International Electronic Commission (IEC) This unit complies to EN 55011 and the reference value is according EN 55011 Group 1 Class B the international electrotechnical committee (IEC).

Classification of product

The equipment complies to the protection degree of Class 1 and for protection against electric shock Type B.

EC Conformity

The COMBI ELEVATOR 2 to which this declaration relates fulfills the essential requirements for safety of medical electrical equipment and follows the provisions of Medical Device Directive 93/42 EEC part 11 para. 3 according the procedure in annex II.
The CE-Mark is only applicable for the product without X-ray components and Bucky.

The declaration of EC-conformity can be sent to you by request:
Write to:
Hans Pausch
Röntgengerätebau
c/o Quality Assurance Sys. Mgr.
Postfach 28 60
D-91016 Erlangen
Fax #: ..49 9131 99 24 22

Enviroment Condition

Surrounding temperatur range	10 C to 40 C
Humidity	20% to 80%
Atmospheric pressure	700 hPa to 1100 hPa

Disposal of equipment

Legal waste disposal regulations may apply to the disposal of this product. To avoid causing damage to the environment and personal injury, we recommend that you contact your Customer Services representative before permanently removing this product from service.

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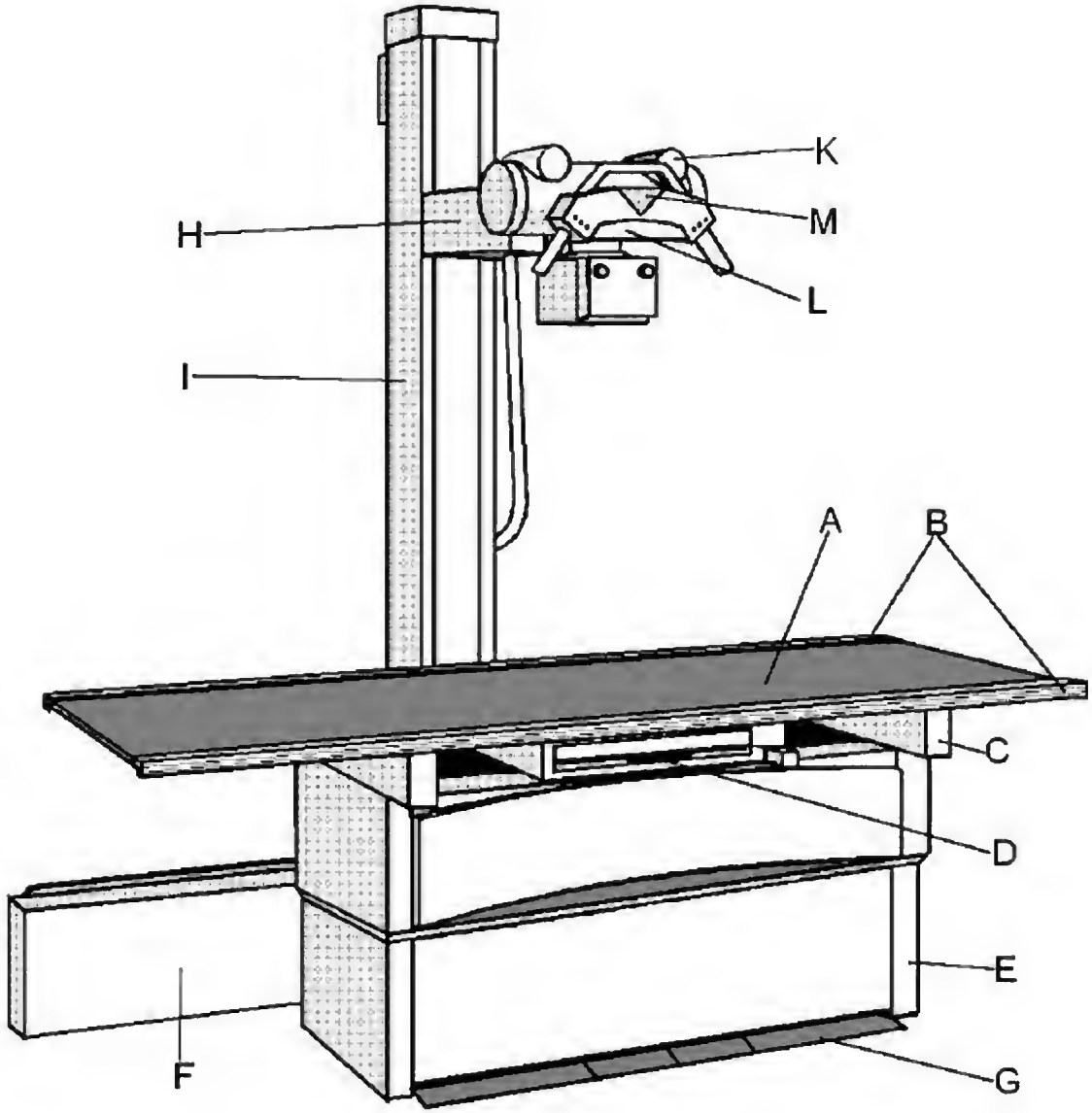
Design Features

Constructional Conception



A Table top, floating, manually movable, scratch-proof
B Profile rail with trim cover, smooth, accepts accessories
C Upper table frame
D Bucky unit, movable
E Table base, solid, vibration-free
F Guide rails for tube stand
G Foot treadle
H Vertical carriage with X-ray tube support arm
I Column, rotatable
K X-ray tube
L Control handle
M Protractor

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General

Short description

The equipment consists of a patient table with coordinate table top and diaphragm carriage, and of a column with X-ray tube, collimator and control arm.

The solid, vibration-free table base and the rail stand with column from one unit.
The large and 2.20 m long, floating table top is manually movable and locks electromagnetically. The table top is provided for a maximum patient weight of 136 kg. For fast and easy positioning of the patient, it allows spacious lateral travel: 60 cm to the left, 50 cm to the right and ± 12 cm transversely.

Especially for patient comfort and easy cleaning, the table top offers a scratch-proof surface (Resopal) and trim-covered, smooth profile rails on both sides, which can accept accessories.

The Bucky carriage takes up cassette trays as supplied by any reknowned manufacturer. In longitudinal direction, it is manually moved and electromagnetically locked. The shortest possible FFD of 70 mm guarantees images of superior geometrical proportion. Low radiation absorption by the table top reduces the X-ray amount. The brake of the Bucky is released by a push-button on the operating handle.

As accessory is a automatic mechanical coupler availabe for automatic connection from the Bucky and tube stand.

The foot treadle along the table base allows the release of the elctromagnetic table top brakes.

The tube stand for the X-ray tube support arm and tube is moved on the rail stand parallel to the longitudinal table axis.

The X-ray tube with collimator and control arm for the tube stand is supported by a lateral arm fixed to the vertical carriage. Vertical movement and rotation of the tube around the longitudinal axis of the lateral arm permit vertical, horizontal or oblique beam projections. Each position is electromagnetically locked.

The X-ray tube with column stand rotates around the vertical column axis and catches mechanically at angles of 0° (basic position), ± 90° (for lateral exposures).

The standard tube support is intended for DIN 6836 flanged plate C.
The max. weight of the X-ray tube and collimator must not exceed 40 kg.

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Rang of use

The equipment is an universal X-ray examination system for doctors´practices as well as for hospitals. It provides high-quality gridded exposures on lying patients. Large travel of the table top and uncomplicated functioning facilitate operation and increase patient comfort. A special cassette holder is available for lateral exposures. With a Bucky wall stand or a cassette stand, exposures can also be made with patients standing or sitting. The total tube stand rotation range of 90° allows exposures with patients on stretchers or in bed.

Without requiring wall and ceiling fixtures, the equipment easily adjust to changes in location.

Prerequisition

For safe and efficient operation of this product the personnel must be familiar with the operating instructions. The chapter on „Safety procedures“ deserves special attention.

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Installation Requirements

Floor space

The system is designed for stationary operation. The approximate floor space required measures 330 cm x 152 cm. An additional 20 cms minimum distance must be kept between tube stand and wall.

Height of room

The tube stand height is 234 cms. Installation requires a minimum room height of 245 cms. The table top of the equipment has a working height of 75 cms above floor.

Power

The system is equipped for single-phase alternating current with fixed installation. Two versions are available, depending on order. The unit is only prepared for solid installation with an all poled separation from the power (ICE 601, Kap. 57.1).
Without transformer, the system corresponds to nominal ratingsas follow:

Nominal voltage:	230 V AC	oder	115/208 VAC
Nominal current:	5 A		10 / 6,25 A
Rated frequency:	50/60 Hz		50 / 60 Hz
Nominal capacity:	1150 VA		1150 VA

Mains

The mains connection requires a 30 mA circuit breaker to be installed by the customer. The electrical installation must meet the relevant legislation, e.g. VDE 0107, IEC/SC 62A.

AL-equivalent

The weakening equivalent of the table top (patient pos. table top) is 0,7 mm.

According to:

DIN EN 60601-1-3 mit 100 kV und HWS 3,7 mm AL
and FDA 21 CFR § 1020.30 (n) mit 100 kV und HWS 2,7 mm AL.

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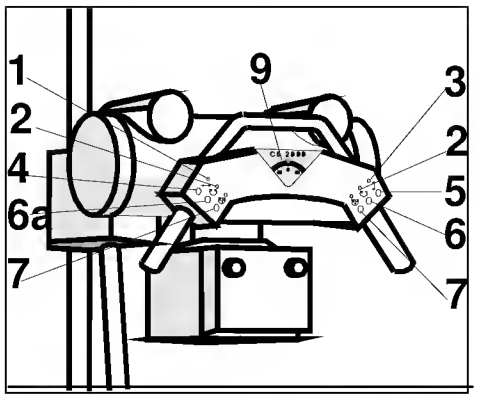
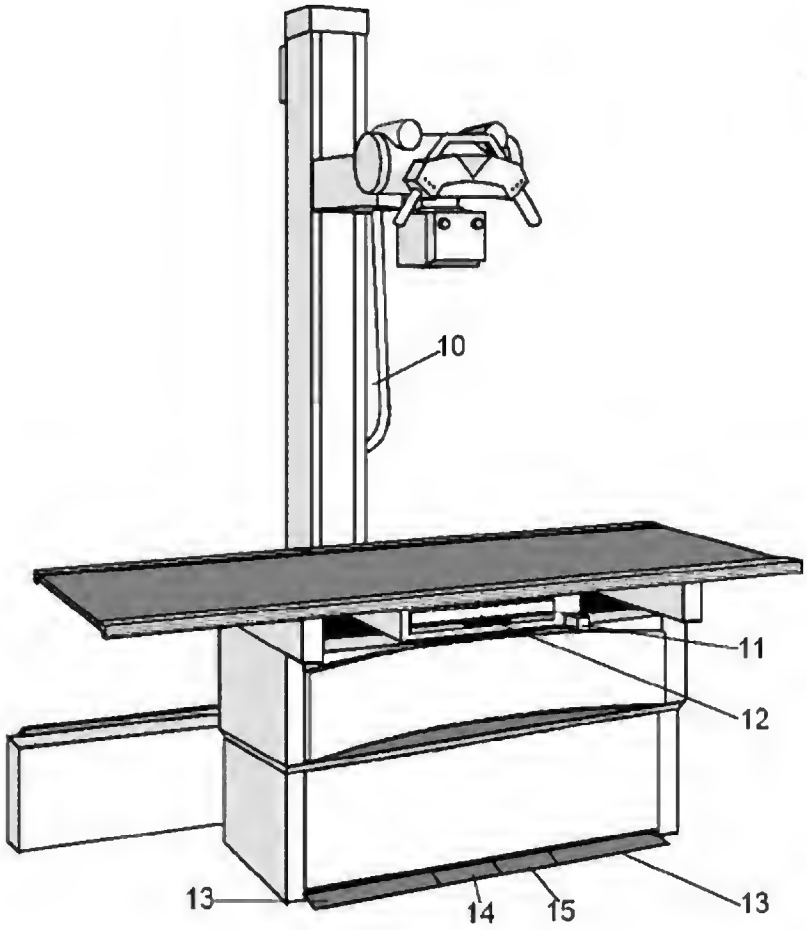
Arrangement





1 Green LED shines when the column is coupled in Bucky movement area
2 Green LED shines when the radiator rotation is catched
2a Green LED lights when the table exposure height
3 Green LED shines when the frist draw FFA is reached.
4 Switch for horizontal movement
5 Switch for vertical movement
6 Switch for tube rotation
6a Safety switch
7 Switch for release of all column brakes
8 Control board with handgrips
9 Protractor
10 Rotation of tube stand by abrupt movement in appropriate direction on controlarm
11 Pushbutton for Bucky
12 Hand grip for cassette tray
13 Foot treadle for table top break
14 Foot treadle for motorized lowering of the table top
15 Foot treadle for motorized raising of the table top

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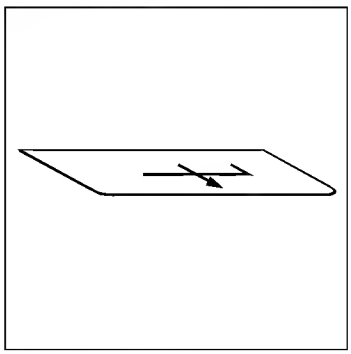
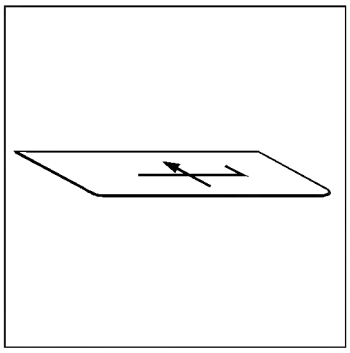
Meaning of Symbols/Function



Foot switch **14** and security switch **6a** for motorised lowering of the table top. The table is moving down as long as the switches are pressed.
The lowering speed with soft start and break is constant. Automatic shutdown of the down motion in end position and in exposure height. Continue of movement after interruption in exposure height.

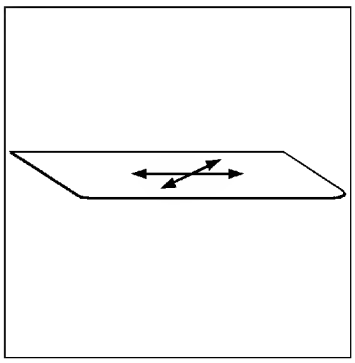
Release foot switch/security switch. Push again.



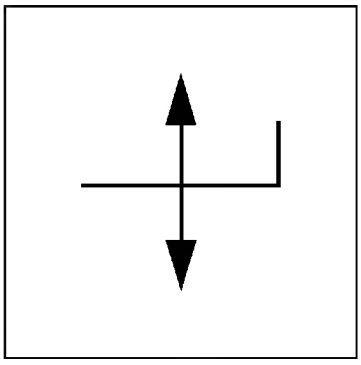
Foot switch **15** and security **6a** for motorised raising of the table top. The table raises as long as the switches are pressed.

The raising speed with soft start and break is constant. Automatic shutdown of the up motion in end position and exposure height.

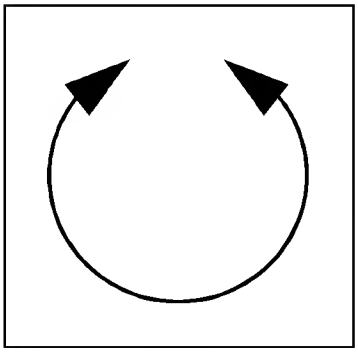
Release foot switch/security switch. Push again.



Foot switch **13** to release the brakes of the floating table top. The table top can be manually shifted longitudinally and transversely as long as the switch is depressed. The table top locks in place when the switch is released.



Security switch **6a**
for motorised raise respectively lowering of the table top.



Switch **6**
to release the brakes for the rotation movement of the X-ray tube. Release of the switch locks the tube in position.

By turning the x-ray tube close to the 0° and 90° position, the LED blinks. Release of the switch causes a exactly motorized positioning of the x-ray tube.

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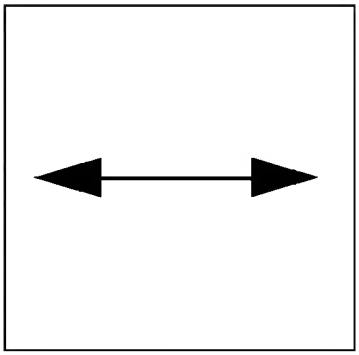
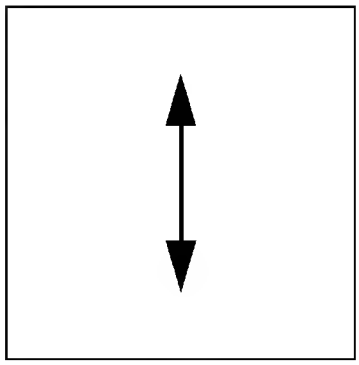
Switch **4**

unlocks the column brake for longitudinal movement. Release of the switch locks the column in place.



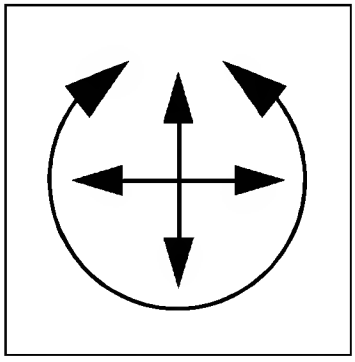
Switch **5**

unlocks the vertical carriage. Release the switch and the vertical carriage will be locked in place again. The motion stops automatically at the preferred vertical SID and can be continued by pressing the switch agin. The motion stops automatically at the preferred vertical SID and can be continued by pressing the switch again.



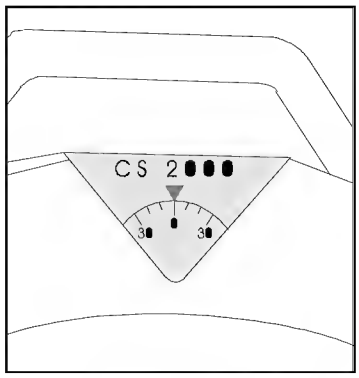
Switch **7**

unlocks the column brakes. Release of the switch locks all movements in place.



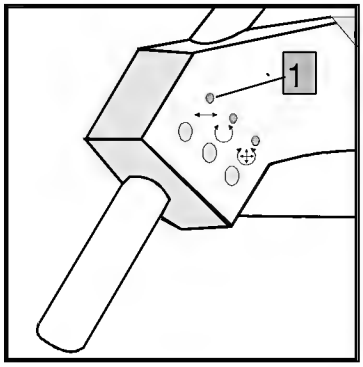
Protractor **9**

indicates the angle of the tube vs. Exposure object.



Indicator LED (green) **1**

lights up to indicate that the Bucky is centered to the column .



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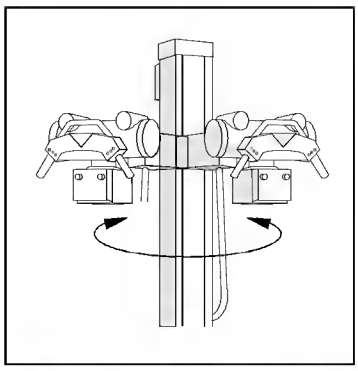
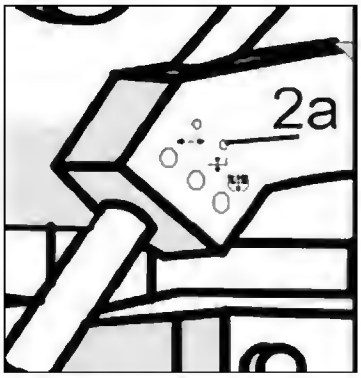
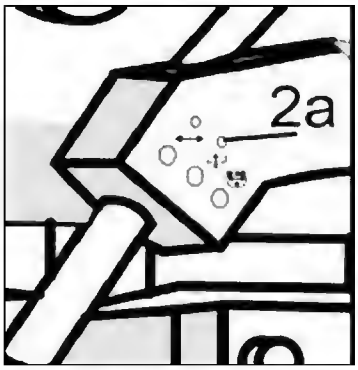


Turn of X-ray tube **10**
The column stand with X-ray tube can be turned round its longitudinal axle to the left or right side by 90 ° with a strong start on both hand grips of the control arm. It catchs at 0° , + 90° each.



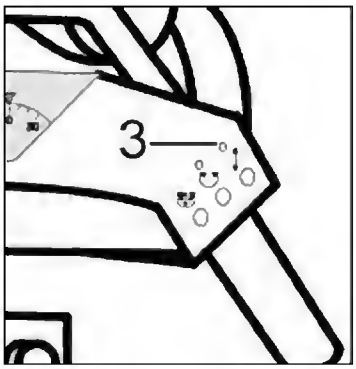
Indicator LED (green) **2a**

lights when the table top is in exposure height.



Indicator LED (green) **2**

indicates an exactly 0° or 90° positioned x-ray tube

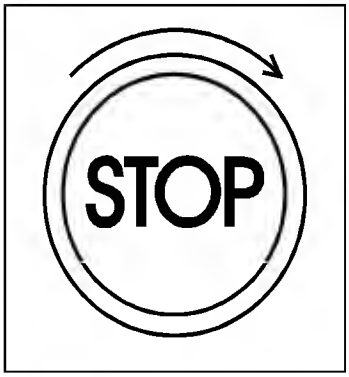


Indicator LED (green) **3**

indicates the adjusted vertical SID

Operation

The equipment is ready for operation when switched on.



Emergency-off

Provided an emergency switch has been installed in the examination room, the red switch button must be pushed immediately in case of danger for patients, operating personnel, or equipment.
After positive elimination of the danger only, turn the red emergency-off switch clockwise to resume operation.

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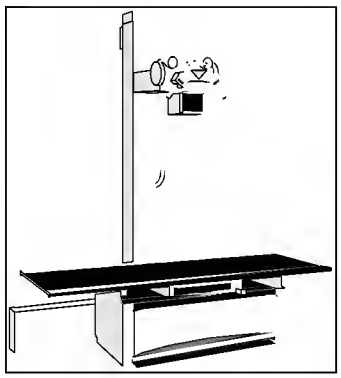
SETTING EXPOSURE POSITION/EXPOSURE

Patient Positioning/ Centering of Bucky, Object and Tube Unit.

Patient Positioning
Note: To prevent injury from the patient sitting down or beeing positioned, move the tube stand and tube out of the critical range before positioning the patient.

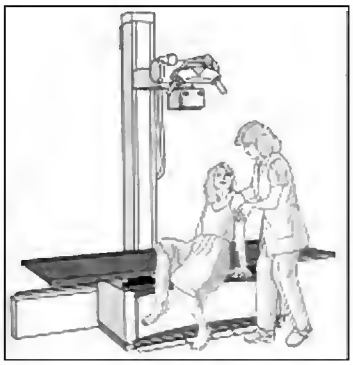


Press the foot switch **13** to unlock the table top brakes.

Move the table top manually floating to the rear stop.

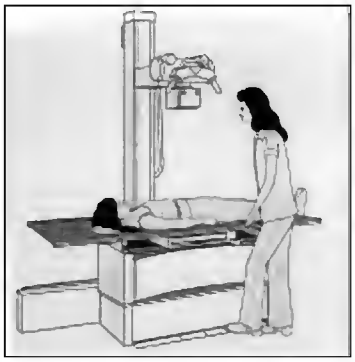
Release the foot switch.

Press the foot switch **14** and the safety switch **6a** simultaneously. The table top is lowered by the motor in a telescopic way.
Release the switch when comfortable working height for patient access or transfer is reached.



Exposure

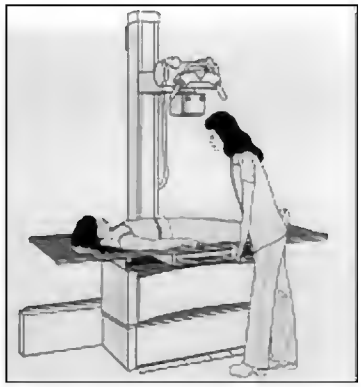
Press the foot switch **15** and the safety switch **6a**. The table top is lifted up by the motor to exposure position. Release the switch after the automatic stop.



Note
When reaching the preset exposure position of the table top, the downward movement is interrupted automatically. To continue movement, release the foot switch. Press again.

Centering of the Bucky

The centering can also be achieved by moving the Bucky carriage into the exposure range.



Note
This moving is necessary when the green lamp of the automatic tube stand/Bucky coupler does not lighten.

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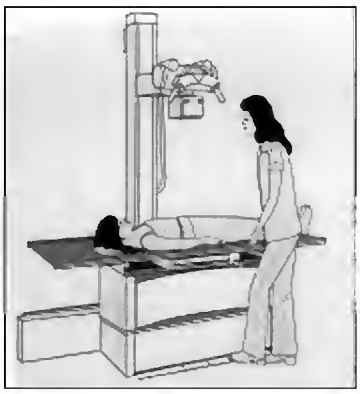
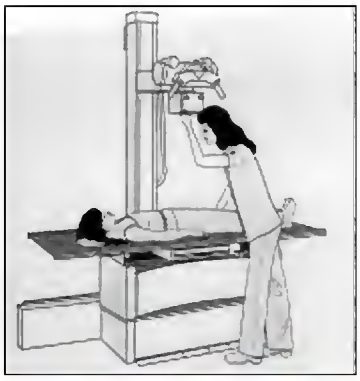


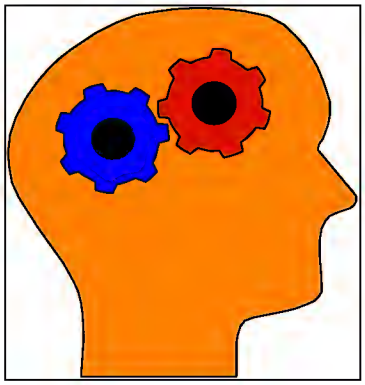
Centering of the object

Move the object into the central beam by adjusting the table top.
For this purpose, press the foot treadle 13 fully down. The brakes of the floating table top are now unlocked. Adjust the table top. Release the foot treadle. The table top is locked in position.



Centering of the radiation field

Use the cassette size sensing for optimal localization of the radiation field of the collimator (operating instruction of the collimator).



Exposure preparation

Insert cassette. Chosse SID (FFD). Set exposure dates on control desk. Control readiness for exposure. Command patient to „hold your breath“.
Note
Do not forget radiation protection protection devices for the patient (lead rubber apron, gonad protection, etc.)

Oblique Exposure

Move tube stand beyond the Bucky range of the automatic range/Bucky coupler. Move the Bucky under the patient. Tilt and center the tube over the Bucky with the indicator light of the collimator switched on.

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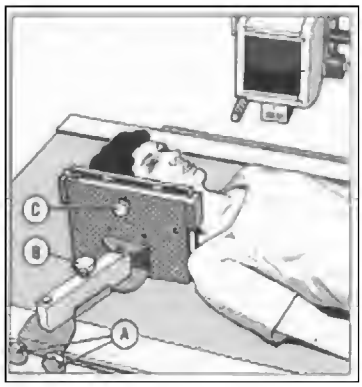
Exposure with Bucky Wall Stand

Move the table top in the direction away from the wall stand. Slide the tube stand towards the wall stand. Rotate the tube to a 90° angle (indication of angle!), switch on the indicator light, then center the tube and adjust the wall stand Bucky to the patient by vertical movement.



Lateral Exposure

For lateral exposures with the cassette holder sideways (cf. page with accessories), rotate the tube stand to a 90° angle. Then rotate the tube to a 90° angle (indication of angle!). Proceed as described above.

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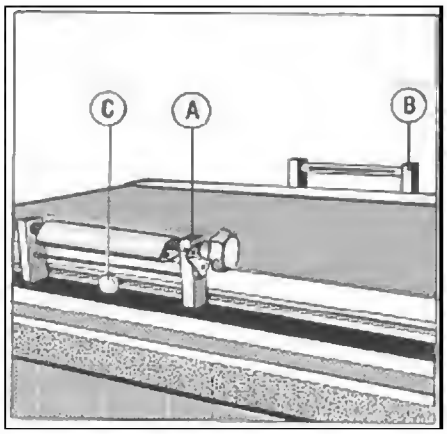
Accessories

Compression Belt / Head Supports / Hip Clamps / Table Mattres

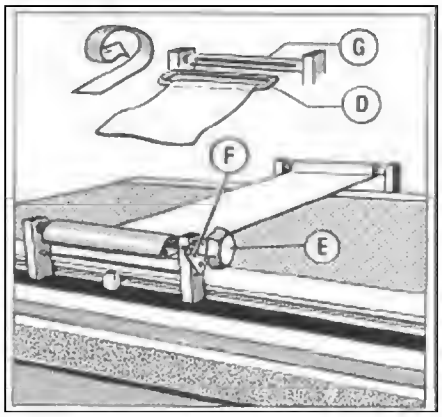


Compression Belt

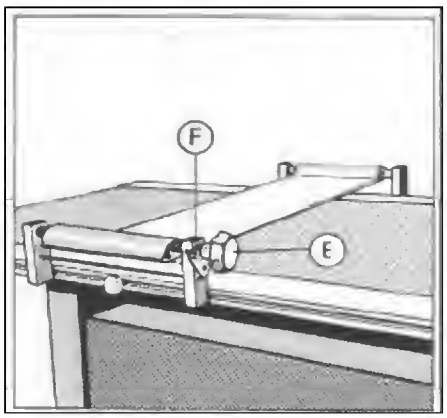
Fastening and application:

Slide support frame **B** into profile rail at wall side or into Bucky profile rail. Turn knob screw to clamp in position.

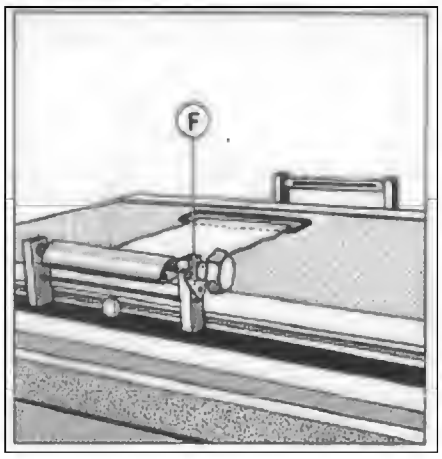
Slide tightener **A** into front profile rail (operator side). Turn hand screw **C** to clamp in working position opposite of **B**



Press ratchet mechanism **F**. Unroll belt and stretch accross patient.



Guide belt through complementary frame and once around frame bar. Fix belt bracket **D** into slot of shaft **G**. Turn ratchet mechanism **E** to tighten belt.



Untightening:

Press locking lever **F**

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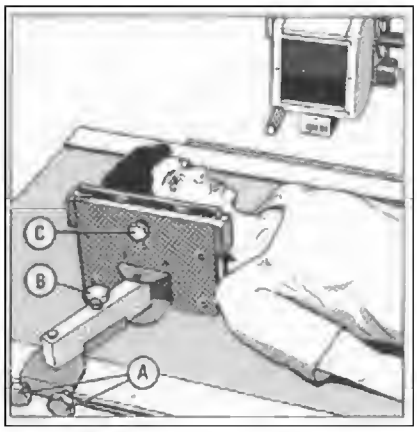
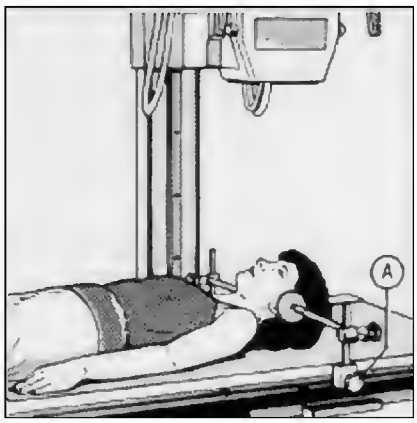
Lateral cassette holder



The lateral cassette holder permits lateral exposures if the tube unit is mounted to a tube swivelling device. The lateral cassette holder is slipped in one of the profile rails.

Grip screw (A): secures the holder at the table top
Grip screw (B): locks the holder setting
Grip screw (C): fixes the lateral position of the cassette clamps.

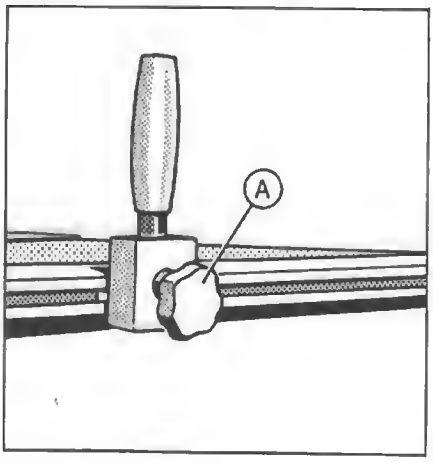
Head Supports



The head supports slide into profile rails of the table or Bucky. The supports can be clamped in any position desired. The patient`s head is fixed to the appropriate exposure position by cushioned plates on adjustable bars.
Hand screw **A**: Clamping head supports to table top or Bucky.

Hand screw **B**: Clamping of head holder

Hand grips



The hand grips are slipped in the profile rails of the table. They may be fixed at any position and offer a reliable hold for the patient.

Grip screw (**A**): secures the grip in place

Important note:

The positioned patient may only hold on to the hand grips. In no case may he put his hands around the edge of the table top.

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Maintenance:

Important note:
Like all technical equipment, this unit requires also a regular maintenance service to increase the safety of the equipment.

Operator´s service and maintenance

The operator has to check the x-ray equipment for defects as listed below:
In case of functional defects or other deviations from the normal operation the equipment has to be switched off at once and the service company has to be informed.
The equipment can not be used before all defects have been eliminated.

Daily routine checks

Check indicator light and operating elements for proper functioning.

Weekly checks

Check all cables and their connections for treaces of wear.

Periodic maintenance

For trouble-free operation of the COMBI ELEVATOR -2 as well as safety for patient and user it is necessary to carry out a technical maintenance from the service company every 12 months.

Please see „technical maintenance“ of the mounting instruction.
The steel rope of the column has to be replaced every three years.

Attention:
In case of failure from components, which can limit the safety of the equipment, original spare parts have to be used.

We recommend that the service personnel is being asked to issue a certificate specifying the kind and extend of work that was done. Also the certificate should show the date of repair, the name of the service company and the signature of the technician.

Cleaning:

The equipment must be switched off before cleaning. Plastic surface should only be cleaned with mild soap. Do not use strong cleaners or solvents as they will damage the finish or blur the lettering.

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At least once a month external parts and exposed tracks on which rollers move should be wiped to remove foreign material that may have accumulated.
DO NOT USE A DAMP CLOTH.
Wipe the tracks with a cloth lightly soaked with light machine oil or WD-40.

To protect the finish, polish the equipment with PURE liquid paste wax. Do not use wax containing a cleaning substance. Polish all enamelled metal surfaces.

Disinfection:

The equipment has to be switched off before disinfection. Only disinfection methods can be used that correspond to the relevant regulations and rules as well as the protection for explosion.
Spray disinfection is not recommended because it can get in the inside of the x-ray equipment.

The Council Directive 93/42/EEC on Medical Devices Article 12

This document is revised at the moment by the council.

However the Article 12 must be followed by the company or the legal person who put this X-ray unit into work.

The user is responsible for compliance and implementation of national deviations in the EU.

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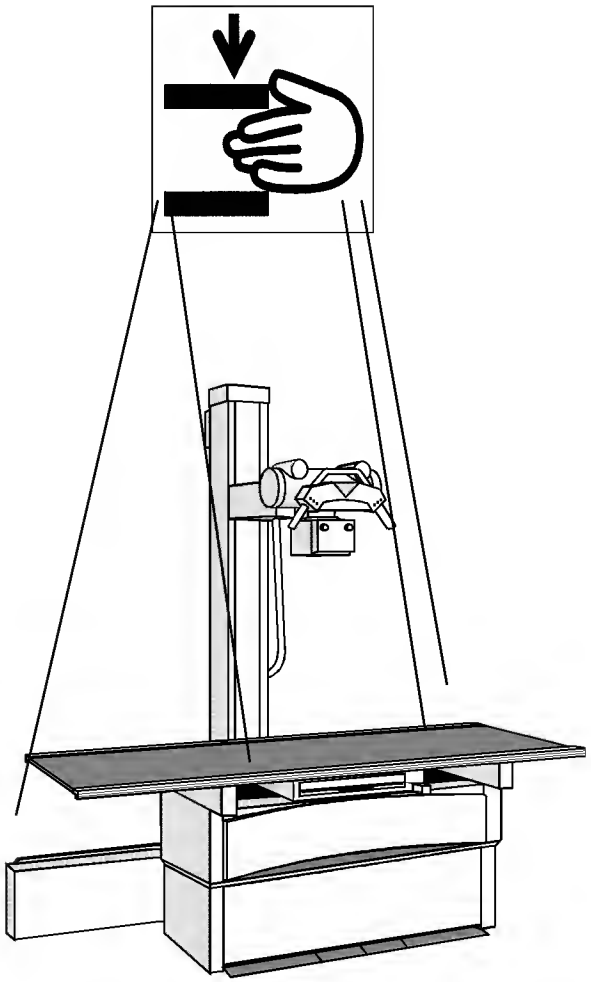
Name Plate Location:

Labeling:



Specifications are subject to change without notice. TV/Ru

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